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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,704	02/21/2006	Monilola Olayioye	DAVI186.004APC	6939

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

NOTIFICATION DATE	DELIVERY MODE
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11/12/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/538,704	Applicant(s) OLAYIOYE ET AL.	
	Examiner CHRISTIAN L. FRONDA	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,33-46 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 35,37-46 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,33,34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 09/16/2008 has been entered.

Claims 26, 33-46, and 49 are pending in the application. Claims 35, 37-46, and 49 have been previously withdrawn from consideration as drawn to a non-election invention.

2. Claims 26, 33, 34, and 36 are under consideration in the instant Office Action. New rejections and new grounds of rejection are presented.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 26, 33, 34, and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting the presence of a breast cancer cell in a subject or in a biological sample from said subject comprising screening for the level of an expression product of a polynucleotide comprising SEQ ID NO: 4 or a polynucleotide that encodes SEQ ID NO: 6; does not reasonably provide enablement for any other embodiment.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited

to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

MPEP § 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the claims encompass a method for detecting the presence of a breast cancer cell in a subject or in a biological sample from said subject comprising screening for the level of any expression product of a polynucleotide having 95% identity to SEQ ID NO: 4 or any polynucleotide that encodes a sequence having 95% identity to SEQ ID NO: 6.

The reference of Whisstock et al. (Q Rev Biophys. 2003 Aug;36(3):307 40; PTO 892) teaches (1) protein function prediction is a difficult problem since homologous proteins often have different and multiple functions; (2) methods for inferring function based on similarity in sequence and/or structure between an unknown protein and one or more well-understood proteins is tenuous and only provide guesses at function; (3) protein function predictions suggest function but do not determine function; (4) the most useful effect of protein function prediction is to guide laboratory experimentation to confirm, refute, or correct the prediction; and (5) protein function prediction from protein sequence and structure is useful but is not a substitute for laboratory experimentation (see entire publication, especially pp. 321-335). The reference of Chica et al. (Curr Opin Biotechnol. 2005 Aug;16(4):378-84; PTO 892) teaches that the complexity of the structure/function relationship in enzymes has proven to be the factor limiting the general application of rational enzyme modification and design, where rational enzyme modification and design requires in-depth understanding of structure/function relationships. The

reference of Sen et al. (Appl Biochem Biotechnol. 2007 Dec;143(3):212-23; PTO 892) teaches *in vitro* recombination techniques such as DNA shuffling, staggered extension process (StEP), random chimera genesis on transient templates (RACHITT), iterative truncation for the creation of hybrid enzymes (ITCHY), recombined extension on truncated templates (RETT), and so on have been developed to mimic and accelerate nature's recombination strategy. However, such directed evolution techniques only enable methods for searching and screening for a polynucleotide having 95% identity to SEQ ID NO: 4 or a polynucleotide that encodes a sequence having 95% identity to SEQ ID NO: 6.

The specification provides guidance and working examples for an isolated polynucleotide of SEQ ID NO: 4 encoding SEQ ID NO: 6. The specification, however, does not provide guidance, prediction, and working examples for making and using the recited polynucleotide having 95% identity to SEQ ID NO: 4 or a polynucleotide that encodes a sequence having 95% identity to SEQ ID NO: 6.

The specification does not provide a correlation between any structure of any polynucleotide having 95% identity to SEQ ID NO: 4 or polynucleotide encoding a sequence having 95% identity to SEQ ID NO: 6 and any biological activity of any peptide having 95% identity to SEQ ID NO: 4 and its role in any cancer such as breast cancer, other than polynucleotide of SEQ ID NO: 4 encoding SEQ ID NO: 6 where overexpression is found in breast cancer cell lines. Further, there is no art-recognized correlation between any structure of any polynucleotide having 95% identity to SEQ ID NO: 4 or polynucleotide encoding a sequence having 95% identity to SEQ ID NO: 6 and any biological activity of any encoded peptide having 95% identity to SEQ ID NO: 4 and its role in any cancer such as breast cancer, other than polynucleotide of SEQ ID NO: 4 encoding SEQ ID NO: 6 where overexpression is found in breast cancer cell lines. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 6 and which nucleotides can vary from SEQ ID NO: 4 that can be correlated with the presence of a breast cancer cell in a subject or in a biological sample from said subject.

Thus, an undue amount of trial and error experimentation must be preformed including making a polynucleotide having 95% identity to SEQ ID NO: 4 or polynucleotide encoding a sequence having 95% identity to SEQ ID NO: 6, determining the biological function of the encoded polypeptide, and determining whether the polynucleotides can be correlated with the

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presence of a breast cancer cell in a subject or in a biological sample from said subject. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a skilled artisan to make and use the claimed invention. Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 26, 33, 34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosen et al., United States Patent Application Publication No. US 2002/0052308. The reference teachings are reiterated below.

Rosen et al. disclose a nucleic acid sequence (SEQ ID NO: 143) that is 100% identical to the nucleic acid sequence of SEQ ID NO:4 (see STIC alignment analysis attached to the previous Office Action filed 06/06/2008).

Rosen et al. teach that the invention relates to newly identified tissue specific cancer associated polynucleotides and the polypeptides encoded by these polynucleotides herein collectively known as "cancer antigens," and to the complete gene sequences associated therewith and to the expression products thereof, as well as the use of such tissue specific cancer antigens for detection, prevention and treatment of tissue specific disorders, particularly the presence of cancer. This invention relates to the cancer antigens as well as vectors, host cells,

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antibodies directed to cancer antigens and recombinant and synthetic methods for producing the same. Also provided are diagnostic methods for diagnosing and treating, preventing and/or prognosing tissue specific disorders, including cancer, and therapeutic methods for treating such disorders. The invention further relates to screening methods for identifying agonists and antagonists of cancer antigens of the invention. The present invention further relates to methods and/or compositions for inhibiting the production and/or function of the polypeptides of the present invention (Abstract). Thus, Rosen et al. teach all the elements of claims 26, 33-34 and 36 and these claims are anticipated under 35 USC 102(b).

The arguments filed 08/06/2008 have been fully considered but are not persuasive. Rosen et al. teaches newly identified tissue specific cancer associated polynucleotides and the polypeptides encoded by these polynucleotides herein collectively known as "cancer antigens," and to the complete gene sequences associated therewith and to the expression products thereof, where Rosen et al. discloses a nucleic acid sequence that is 100% identical to the nucleic acid sequence of SEQ ID NO:4. One skilled in the art in view of the teachings of Rosen et al. would know that the taught polynucleotides including SEQ ID NO: 143 would be associated with cancer such as breast cancer.

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

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9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/

Primary Examiner

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